



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Fasenra® prefilled syringe and Fasenra Pen™

benralizumab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about FASENRA prefilled syringe and FASENRA PEN prefilled pen (collectively called FASENRA in this document). It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you being given FASENRA against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor, nurse or pharmacist.

Read this leaflet carefully before you have FASENRA. Keep it in a safe place as you may need to read it again.

What FASENRA is used for

FASENRA is used to treat a type of asthma -eosinophilic asthma -which is where patients have too many eosinophils in the blood and lungs. FASENRA is used together with other medicines you take regularly to treat your asthma (inhaled corticosteroids plus other asthma medicines - for example a daily preventer puffer/inhaler).

FASENRA contains the substance benralizumab, a humanised monoclonal antibody. Benralizumab works by binding to a specific receptor on the eosinophil called the interleukin-5 (IL-5) receptor. By binding to this receptor FASENRA reduces the number of eosinophils in your blood and lungs. Eosinophils are a type of white blood cell that may make your asthma worse by causing inflammation in the lungs.

If you are already using other asthma medicines (such as your daily preventer puffer/inhaler) but your asthma is not well controlled by these medicines, then FASENRA may help to reduce the number of asthma attacks (exacerbations) and may also make it easier for you to breathe normally. If you are taking medicines called oral corticosteroids (eg prednisolone) FASENRA may also help reduce the oral corticosteroid dosage you need to take each day to control your asthma.

You must not stop taking or reduce the dose of your other asthma medicines unless your doctor advises you to.

FASENRA does not treat acute asthma symptoms such as a sudden asthma attack. You will still need your reliever puffer/inhaler.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed FASENRA for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you have FASENRA

When you must not have FASENRA

Do not have FASENRA if you have an allergy to benralizumab or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

You should not have this medicine after the expiry date printed on the pack, if the packaging is torn or shows signs of tampering or there

are visible signs of deterioration of the product.

If your injection is given by a doctor, nurse or pharmacist then they will usually check that the expiry date printed on the pack has not passed and that the packaging is not torn or showing signs of tampering.

However, if you are given FASENRA by a pharmacist and it has expired or is damaged, return it to your pharmacist for disposal.

FASENRA is not recommended for children aged under 12 years, as the safety and effectiveness are not known in this population.

If you are not sure whether you should have this medicine, talk to your doctor, nurse or pharmacist.

Before you start on it

Ask your doctor, nurse or pharmacist if you have any questions about your personal Asthma Action Plan.

Your doctor or nurse should give you a personal Asthma Action Plan to help manage your asthma. This plan will include what medicines to use regularly to control your asthma (eg preventer puffers/inhalers, as well as FASENRA), as well as what reliever medicines to use when you have sudden asthma attacks.

Tell your doctor if you have any allergies including allergies to other medicines, foods, preservatives or dyes, animals or plants.

Tell your doctor if you have or have had any of the following medical conditions:

- an allergic reaction to benralizumab
- an infection caused by parasites (eg parasitic worms) or if you live in/are travelling to an area where parasitic infections are common as this medicine may weaken your ability to fight certain types of parasitic infections. The parasitic infection should be treated before you are given FASENRA.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

It is not known whether the ingredients of FASENRA can pass into breast milk. The effects of FASENRA in pregnant women or their unborn babies are not known. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you have FASENRA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This includes all the medicines that you use for your asthma including preventer and reliever medicines.

It is possible that some medicines and FASENRA may interfere with each other. Your doctor and pharmacist can advise you.

FASENRA has been used together with other commonly used asthma medicines.

Do not suddenly stop taking your asthma medicines once you have started FASENRA.

Some medicines (especially corticosteroids) must be stopped gradually, under the supervision of your doctor and based on your response to FASENRA.

How FASENRA is given

FASENRA is given as an injection into the fat layer just under the skin (subcutaneous)

If your doctor or nurse have recommended that you/your caregiver can give your injection, make sure you/your caregiver reads the 'Instructions for Use' carefully before using FASENRA (see 'How it is given' section below).

Follow all directions given to you/your caregiver by your doctor or nurse carefully.

How much is given and how long to take it

The recommended dose for adults and children who are 12 years and over is 30 mg (one injection -as either FASENRA PEN or FASENRA prefilled syringe). You will need one injection every 4 weeks for the first 3 doses, then one injection every 8 weeks after that.

Continue FASENRA for as long as your doctor tells you.

FASENRA helps to control your asthma but does not cure it. It is important to keep taking your medicine even if you feel well.

How it is given

Each pack of FASENRA PEN and FASENRA prefilled syringes has an *Instructions for Use* booklet included. Read the *Instructions for Use* booklet carefully before you start using FASENRA.

The injections are usually given in your thigh or abdomen, however when given by someone else (for example a caregiver or your doctor, nurse or pharmacist), it may also be given in the upper arm.

Do not try to inject yourself in the arm.

If you miss a dose

If you have missed a dose of FASENRA contact your doctor, nurse or pharmacist as soon as possible. They will tell you what you need to do. You may need to reschedule your appointment if your injection is given to you by a doctor or nurse. If you/your caregiver give the injection, do not take your missed dose unless your doctor, nurse or pharmacist tell you to.

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you have trouble remembering your appointments or when to

inject yourself, ask your doctor, nurse or pharmacist for some hints.

If you are given too much (overdose)

If FASENRA is given under the close supervision of a doctor, nurse or pharmacist it is unlikely that you will be given too much.

If you are concerned that you have been given too much FASENRA, tell your doctor, nurse or pharmacist immediately.

Telephone the Poisons Information Centre (telephone 13 11 26) for advice if you think that you or anyone else may have taken too much FASENRA. Do this even if there are no signs of discomfort or poisoning.

While you are having FASENRA

Things you must do

If you have an Asthma Action Plan follow it closely at all times. If your asthma is uncontrolled or worsening tell your doctor.

If you are about to be started on any new medicine, remind your doctor, nurse and pharmacist that you are having FASENRA.

Tell any other healthcare professionals including doctors, dentists, nurses and pharmacists who treat you that you are having this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are having this medicine.

It may affect other medicines used during surgery.

If you become pregnant while having this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are having this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's and/or hospital's appointments so that you don't miss any doses and your progress can be checked.

Things you must not do

Do not have FASENRA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop having FASENRA unless your doctor advises you to.

Interrupting or stopping FASENRA treatment may cause your asthma symptoms and asthma attacks to come back or become more frequent.

Do not stop using or reduce the dose of your other asthma medicines unless your doctor advises you to.

Some medicines (especially corticosteroids) must be stopped gradually, under the supervision of your doctor and on your response to FASENRA.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are having FASENRA.

This medicine helps most people with eosinophilic asthma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- headache
- sore throat

- fever/high temperature
- injection site reactions (eg pain, redness, itching, swelling near where the injection was given).

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If you think you are having an allergic reaction to FASENRA tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital.

Some of the symptoms of an allergic reaction may include:

- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)

Allergic reactions may occur within minutes or hours after an injection or may even occur several days after an injection.

You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After having FASENRA

Storage

Keep FASENRA in the refrigerator at 2°C to 8°C. Do not freeze, shake or expose to heat. FASENRA should be kept sealed in the original package to protect it from light.

FASENRA may be kept at room temperature up to 25°C for no more than 14 days. This is important whether travelling by car, bus, train, plane or any other form of transport. FASENRA must be used within 14 days or discarded.

There is a space on the carton to write the date it is removed from the refrigerator.

Keep it where children cannot reach it.

Disposal

After injecting FASENRA immediately throw away the used prefilled syringe in a special 'sharps' disposal container as instructed by your doctor, nurse or pharmacist.

If your doctor tells you to stop using FASENRA or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FASENRA PEN contains 1 mL of solution in a clear glass type I prefilled syringe inside a pen (autoinjector). Its colour may vary from colourless to yellow, and it may contain white particles.

The pen includes a stainless-steel needle, with a FluoroTec (non-latex) coated plunger stopper and a needle safety guard inside the pen (autoinjector).

FASENRA PEN is available in packs containing 1 FASENRA PEN (a single dose).

FASENRA prefilled syringe contains 1 mL of solution in a clear glass type I prefilled syringe. Its colour may vary from colourless to yellow, and it may contain white particles.

The glass prefilled syringe includes a stainless-steel needle, with a FluoroTec (non-latex) coated plunger stopper and a needle safety guard.

FASENRA prefilled syringe is available in packs containing 1 prefilled syringe (a single dose).

Ingredients

FASENRA PEN and FASENRA prefilled syringe contain 30mg of benralizumab as the active ingredient.

Other ingredients include:

- histidine
- histidine hydrochloride monohydrate
- trehalose
- polysorbate 20
- water for injections

This medicine does not contain latex, lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone: 1800 805 342

This leaflet was prepared on 9 December 2019

The Product Information document prepared for use by healthcare providers can be found on the Therapeutic Goods Administration (TGA) website – www.ebs.tga.gov.au/

Australian Registration Number:

FASENRA PEN – AUST R 313902

FASENRA prefilled syringe - AUST R 285718

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Instructions for Use

**FASENRA®
benralizumab 30mg/1mL
For subcutaneous injection
Single-dose pre-filled syringe**

You and your doctor or nurse should decide if you should inject Fasenra yourself. You or your caregiver

should receive training on the right way to prepare and inject Fasenra. Follow all directions given to you by your doctor or nurse carefully.

Read this *Instructions for Use* booklet carefully all the way to the end before you start using your Fasenra prefilled syringe and each time you get a new Fasenra prefilled syringe.

There may be new information. This information does not take the place of talking to your doctor, nurse or pharmacist about your medical condition or your treatment.

You should also read the Consumer Medicine Information (CMI; included in the pack) for further information about this medicine such as what it is used for, possible side effects and when to use it. More recent information may be available – the most recent CMI is available from your pharmacist and also at www.astrazeneca.com.au/CMI (Australia).

If you or your caregiver have any questions about Fasenra or your medical condition talk to your doctor, nurse or pharmacist. You can also contact the Asthma Foundation in your State who provide information about asthma treatment and management.

Important information

Store your Fasenra prefilled syringe in a refrigerator between 2°C to 8°C. To protect it from light it should be stored in its carton until you are ready to use it.

Fasenra maybe kept at room temperature up to 25°C for no more than 14 days. This is important whether travelling by car, bus, train, plane or any other form of transport. Fasenra must be used within 14 days or discarded (see Step 9 - Dispose of the used prefilled syringe safely). There is a space on the carton to write the date it is removed from the refrigerator.

Do not use your Fasenra prefilled syringe if:

- it has been frozen
- if the syringe itself has been dropped or damaged
- the security seal on the carton has been broken or the packaging has been torn or shows signs of tampering, or there are visible signs of deterioration of the products
- the expiry date (EXP) printed on the pack has passed

Do not:

- shake your prefilled syringe
- share or re-use your prefilled syringe

If any of the above happens, throw away your prefilled syringe in a puncture-resistant (sharps) container (see Step 9 - Dispose of the used prefilled syringe safely) and use a new prefilled syringe.

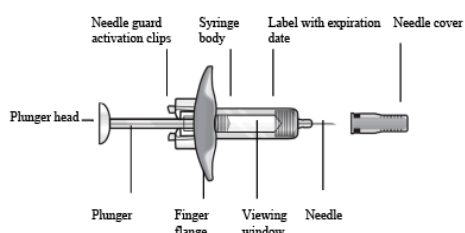
Each Fasenra prefilled syringe contains 1 dose of Fasenra that is for one-time use only.

Keep Fasenra and all medicines out of the sight and reach of children.

Your Fasenra prefilled syringe

Do not remove the needle cover until you have reached Step 6 of these instructions and are ready to inject Fasenra.

Do not touch the needle guard activation clips to keep from activating the safety device (needle guard) too soon.



Step 1 - Gather Supplies

Before your injection, gather the following and set up on a clean, flat surface:

- Your Fasenra prefilled syringe, which may need to be removed from the refrigerator
- The following items which are not included within your Fasenra pack:
 - a new alcohol wipe
 - a new, clean, dry cotton ball or gauze
 - a puncture-resistant sharps container (see Step 9 - Dispose of the used prefilled syringe safely)



Step 2 - Prepare to use your prefilled syringe

Check the expiry date (EXP) on the pack.

Do not use if the expiry date has passed.

If your prefilled syringe has been in the refrigerator, let it warm up at room temperature for about 30 minutes before giving the injection.



Do not warm the prefilled syringe in any other way. For example, do not warm it in a microwave or hot water, direct sunlight or put it near other heat sources.

Use your Fasenra prefilled syringe within 14 days of removing from the refrigerator.

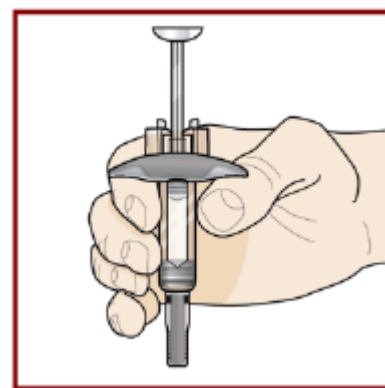
Step 3 - Check the liquid

Open the carton. Peel off the entire lid from the plastic tray.

Grasp the syringe body (not the plunger) to remove the prefilled syringe from its tray.

Look at the liquid through the viewing window.

The liquid should be clear and colourless to yellow. It may contain small white particles.

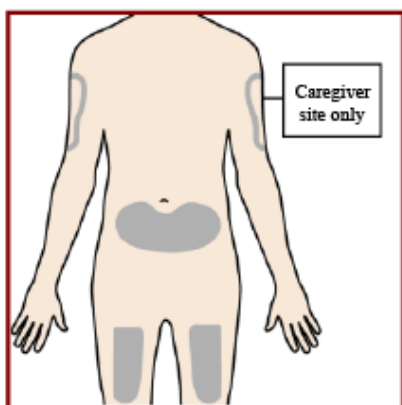


Do not inject Fasenra if the liquid is cloudy, discoloured, or contains large particles.

You may see a small air bubble in the liquid. This is normal. You do not need to do anything about it.

Step 4 - Choose the injection site

The recommended injection site is the front of your thigh. You may also use the lower part of your abdomen.



Do not inject:

- into the 5 cm area around your belly-button
- where the skin is tender, bruised, scaly or hard
- into scars or damaged skin
- through clothing

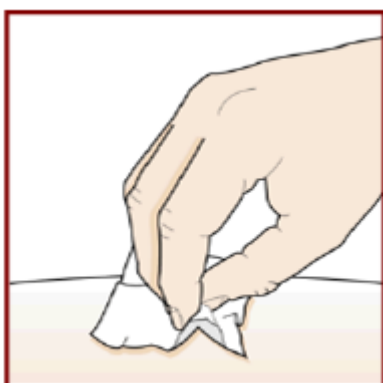
A caregiver may inject you in the upper-arm, thigh, or abdomen. **Do not** try to inject yourself in the arm.

For each injection, choose a different site that is at least 3 cm away from where you last injected.

Step 5 - Clean the injection site

Wash your hands well with soap and water.

Clean the injection site with an alcohol wipe in a circular motion. Let it air dry.

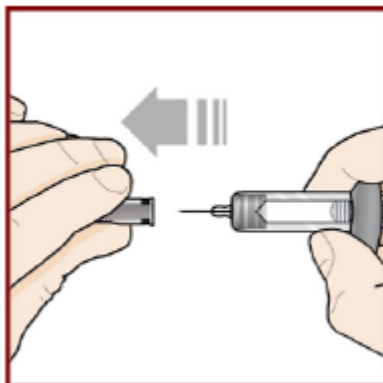


Do not touch the cleaned area before injecting.

Do not fan or blow on the cleaned area.

Step 6 - Pull off the needle cover

Hold the syringe body with 1 hand, and carefully pull the needle cover straight off with your other hand.



Do not hold the plunger or plunger head while removing the needle cover.

Put the needle cover aside to throw away later.

You may see a drop of liquid at the end of the needle. This is normal.

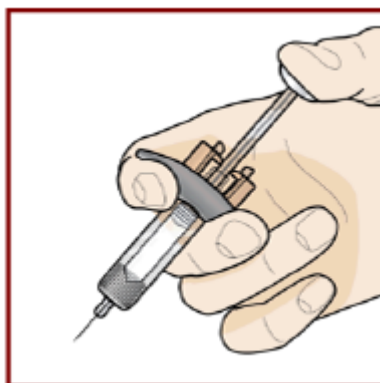
Do not use the syringe if it is dropped without the needle cover in place or if the needle is damaged or dirty.

Do not touch the needle, or let it touch any surface.

Go straight on to the next steps, without delay.

Step 7 - Inject Fasenra

Hold the prefilled syringe in 1 hand as shown.



Use your other hand to gently pinch and hold the area of skin where you

want to inject. This creates a firmer surface.

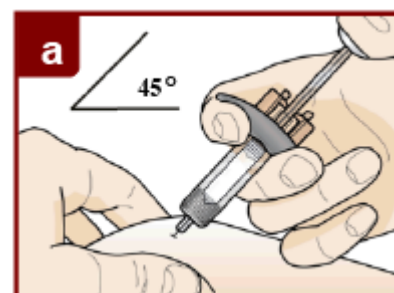
Do not press down on the plunger until the needle is completely inserted into the skin.

Do not pull back on the plunger at any time.

Inject Fasenra by following the steps in figures a, b and c.

Use a quick, dart-like motion to insert the needle into the pinched skin.

Insert the needle at an angle of 45 degrees.



Use your thumb to push down on the plunger head.

Keep pushing until it is down as far as it will go. This is to make sure you inject all of the medication.



Keep your thumb pressed down on the plunger head as you take the needle out of the skin.

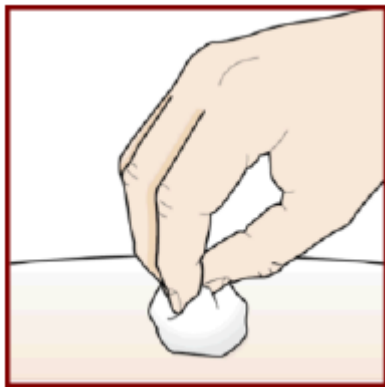
Slowly ease up on the plunger until the needle guard covers the needle.



Step 8 - Check the injection site

There may be a small amount of blood or liquid where you injected. This is normal.

Gently hold pressure over your skin with a cotton ball or gauze until the bleeding stops.



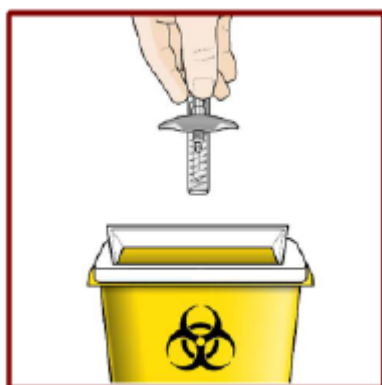
Do not rub the injection site.

If needed, cover the injection site with a Band-aid/plaster.

Step 9 - Dispose of the used prefilled syringe safely

Each prefilled syringe contains a single dose of Fasenra and **cannot be re-used**.

Put your used prefilled syringe in a puncture-resistant sharps container right away after use.



The sharps container needs to be a puncture-resistant container that is large enough to hold the entire syringe. Be sure that the container has a lid. You may use a biohazard

container, another hard-plastic container or a metal container.

A container is not included in the carton. Your pharmacist may have biohazard/sharps containers for purchase or can tell you where you may be able to get them or what else you may be able to use. Your pharmacist can also tell you how to safely throw away the container with used syringes.

Do not throw away used prefilled syringes in your household rubbish or recycling bin.

Do not re-cap the used prefilled syringe. You can throw away the cap and other used supplies in your household rubbish.

Do not throw away your used sharps container in your household rubbish or recycling bin.

For all enquiries contact AstraZeneca on 1800 805 342 (Australia).

This Instructions for use booklet was prepared 9 December 2019.

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